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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,086	03/07/2000	Miladin P. Lazarov	11699-002001	9173

7590 12/28/2004

John C. Linderman
McCORMICK, PAULDING & HUBER
City Place II, 185 Asylum Street
Hartford, CT 06103-4102

EXAMINER	
KRUER, KEVIN R	

ART UNIT	PAPER NUMBER
1773	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/521,086	LAZAROV ET AL.	
	Examiner	Art Unit	
	Kevin R Kruer	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-39* is/are pending in the application.

4a) Of the above claim(s) *24-31,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Note: Prosecution of the application has been re-opened to address a 35 U.S.C. 112, second paragraph rejection that was not applied in the Non-final Office Action mailed 4/9/2004.

Election/Restrictions

1. Newly submitted claims 37 and 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 37 and 38 are drawn to a method of using the product. Applicant elected to prosecute the claims drawn to the product in the Response to the Election/Restriction requirement filed on March 26, 2001. MPEP 818.02(a) states that the claims originally acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination which has been filed in the application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Applicant's election of the product claims (canceled claims 20-23) in the reply filed on 10/6/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/6/2004.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 32-36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not teach a coated article that "prevents" intimal hyperplasia.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "steel 1440" is indefinite. Said term is not defined in the originally filed specification and does not have an art-accepted meaning.

Specification

8. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. ***Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.*** If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 32, 35, 36, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/25960 (herein referred to as "Lazarov") in view of Guire (US 4,973,493). Herein, US 6,110,204 (the national stage application of Lazarov) is relied upon as an English translation of WO 96/25960.

Lazarov teaches implants for use in the human body. The implants comprise a substrate and a coating that contains chemical compounds of the formula of MN_xO_y, wherein (M) is a metal selected from Group IVA of the periodic table (Ti, Zr, and Hf) (abstract). The formula of MN_xO_y is understood to read on the claimed titanium nitrid oxide. The implant can comprise a stent (col 1, line 10). The coating should have a thickness of from 3nm to 3mm, most preferably 30-71nm and has a specific resistance ranging from 30-30000uΩcm (col 3, lines 21-33).

Lazarov teaches that coagulating inhibiting agents may be applied to the coating (col 5, lines 52+) but does not specifically teach that albumin may be applied. However, Guire teaches that surfaces of implantable items have been modified to prevent undesirable protein adhesion by coating the surface with albumin (col 1, lines 57+), such as human albumin (col 10, lines 4+). The albumin coating enhances the item's thromboresistance (i.e. it inhibits coagulation). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply albumin to the

surface of the implant taught in Lazarov. The motivation for doing so would have been to improve the thromboresistance of the implant.

The implant taught by Lazarov in view of Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin. The examiner takes this position because the implant taught by Lazarov in view of Guire comprises the same layers comprising the same compositions as the claimed implant. The courts have held that the method of making a product does not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making the product inherently results in a materially different product.

With regard to the limitation that the coated article "prevents or reduces intimal hyperplasia at the site of implantation, insertion or attachment," the examiner takes the position that said property is a latent property of the article rendered obvious by the prior art. Specifically, the article rendered obvious by the prior art meets all the structural limitations of the claimed articles, including the titanium nitrid oxide coating and the albumin coating. Since the mere recognition of latent properties in the prior art does not render non-obvious an otherwise known invention, the rejection is maintained.

11. Claims 32, 33, 35, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock (US 3,755,823) in view of WO 96/25960 (herein referred to as "Lazarov") and Guire (US 4,973,493).

Hancock teaches a coronary stent (abstract) comprised of stainless steel (col 2, line 68).

Hancock does not teach that the coronary stent should be coated with the claimed titanium nitrid oxide layer. However, Lazarov teaches an implant coating that significantly reduces the activation of blood coagulation accompanied by the formation of thrombi and bio-film (col 2, lines 7+). The coating comprises a material that contains chemical compounds of the formula of MN_xO_y, wherein (M) is a metal selected from group IV A of the periodic table (Ti, Zr, and Hf) (abstract). The formula of MN_xO_y is understood to read on the claimed titanium nitrid oxide. The coating should have a thickness of from 3nm to 3mm, most preferably 30-71nm and has a specific resistance ranging from 30-30000uΩcm (col 3, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the coating taught in Lazarov to the coronary stent taught in Hancock. The motivation for doing so would have been to significantly reduce the activation of blood coagulation accompanied by the formation of thrombi and bio-film.

Lazarov teaches that coagulating inhibiting agents may be applied to the coating (col 5, lines 52+) but does not specifically teach that albumin may be applied. However, Guire teaches that the surfaces of implantable items have been modified to prevent undesirable protein adhesion by coating the surface with albumin (col 1, lines 57+), such as human albumin (col 10, lines 4+). The albumin coating enhances the implant's thromboresistance (i.e. it inhibits coagulation). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply human albumin to the surface of the coronary stent taught by Hancock in view of Lazarov. The motivation for doing so would have been to improve the thromboresistance of the stent.

The implant taught by Hancock in view of Lazarov and Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin. The examiner takes this position because the implant taught by Hancock in view of Lazarov and Guire comprises the same layers comprising the same compositions as the claimed implant. The courts have held that the method of making a product does not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making the product inherently results in a materially different product.

With regard to the limitation that the coated article "prevents or reduces intimal hyperplasia at the site of implantation, insertion or attachment," the examiner takes the position that said property is a latent property of the article rendered obvious by the prior art. Specifically, the article rendered obvious by the prior art meets all the structural limitations of the claimed articles, including the titanium nitrid oxide coating and the albumin coating. Since the mere recognition of latent properties in the prior art does not render non-obvious an otherwise known invention, the rejection is maintained.

Response to Arguments

Applicant's arguments filed October 6, 2004 have been fully considered but they are not persuasive.

Applicant argues that the problem solved by applicant's invention as claimed is to prevent or reduce intimal hyperplasia at the site of implantation, insertion, or attachment. Applicant argues said problem is entirely different than fibrinogen

activation or coagulation inhibition which are the problems set forth in the cited references. Applicant argues that unless there is some suggestion in the cited references that the approach taken by Applicant to generate an improved implantable article will work to prevent or reduce intimal hyperplasia at the site of implantation, the approach is not obvious. Applicant's arguments are noted. However, Applicant's arguments are not persuasive because it is not necessarily that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.

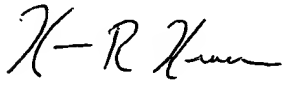
Applicant further argues that applicant further argues that Lazarov or Guire give little or no indication of the effect of the instantly claimed implant on intimal hyperplasia. The examiner agrees. However, the examiner takes the position that said property is a latent property of the article rendered obvious by the prior art. Specifically, the article rendered obvious by the prior art meets all the structural limitations of the claimed articles, including the titanium nitrid oxide coating and the albumin coating. Since the mere recognition of latent properties in the prior art does not render non-obvious an otherwise known invention, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin R Kruer whose telephone number is 571-272-1510. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin R. Kruer
Patent Examiner-Art Unit 1773